

Notice of Allowability

Application No.

09/600,012

Examiner

Eric F. Winakur

Applicant(s)

PHILLIPS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 22 June 2005 (resubmission of filing of 3 June 2004).
2. ☒ The allowed claim(s) is/are 10-19, 21-29 and 31-40.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>11/8/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ashley Henry (Reg. No. 53,709) on 31 August 2005. Applicant agreed to amend claims 10 and 21 to positively recite the predicting step. The term "whereby" will be replaced with "wherein" throughout the claims. Claims 31 and 36 will be amended for purposes of readability; no change in scope is intended by the amendments.

The application has been amended as follows:

Claim 10 has been amended as follows:

10. A method of monitoring the cerebral cellular environment of a patient for prognosis and for providing information for treatment comprising:

providing an opening in the skull of said patient;

inserting a catheter through said opening into a region of cerebrospinal fluid (CSF) within said skull of said patient, said catheter having a flow section capable of permitting said CSF to flow therein;

positioning said flow section of said catheter into said region of CSF;

placing at least one sensor capable of sensing pH into said flow section within said catheter to enable said CSF to flow adjacent said sensor so that said sensor may sense at least one characteristic, including pH, of said CSF; [and]

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monitoring changes of said at least one characteristic of said CSF within the initial 48 hours following head trauma; and [to predict the outcome of the head trauma] predicting the outcome of the head trauma based on the monitored changes.

In claim 11, line 1, "whereby" was changed to -- wherein --.

In claim 13, line 1, "whereby" was changed to -- wherein --.

In claim 16, line 1, "whereby" was changed to -- wherein --.

In claim 17, line 1, "whereby" was changed to -- wherein --.

In claim 19, line 1, "whereby" was changed to -- wherein --.

Claim 21 was amended as follows:

21. A method of monitoring at least one characteristic of cerebrospinal fluid (CSF) of a patient for prognosis and for providing information for treatment comprising:
providing an opening in the skull of said patient through which a region of CSF is accessible;

inserting a catheter through said opening into said region of CSF in said patient, said catheter having a flow section capable of permitting said CSF to flow therein;

positioning said flow section of said catheter into said region of CSF;

placing at least one sensor capable of sensing pH into said flow section within said catheter to enable said CSF to flow adjacent said sensor so that said sensor may sense at least one characteristic, including pH, of said CSF; [and]

monitoring changes of said at least one characteristic of said CSF within the initial 48 hours following head trauma; and [to predict the outcome of the head trauma] predicting the outcome of the head trauma based on the monitored changes.

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In claim 23, line 1, "whereby" was changed to -- wherein --.

In claim 26, line 1, "whereby" was changed to -- wherein --.

In claim 27, line 1, "whereby" was changed to -- wherein --.

In claim 29, line 1, "whereby" was changed to -- wherein --.

In claim 31, line 8, "whereby", "permitting", and "of" (second occurrence) were deleted and "is" was changed to -- further being --.

In claim 32, line 1, "whereby" was changed to -- wherein --.

In claim 33, line 1, "whereby" was changed to -- wherein --.

In claim 34, line 1, "whereby" was changed to -- wherein --.

In claim 36, line 9, "whereby", "permitting", and "of" (second occurrence) were deleted and "is" was changed to -- further being --.

In claim 37, line 1, "whereby" was changed to -- wherein --.

In claim 38, line 1, "whereby" was changed to -- wherein --.

In claim 39, line 1, "whereby" was changed to -- wherein --.

2. The following is an examiner's statement of reasons for allowance: Applicant's remarks filed with the amendment of 22 June 2005 are noted. With regard to claims 31, 34, 36, and 39, Examiner has reviewed the combination of Millar, Kovacs, and Crothall and notes that the measurements performed by Kovacs and Crothall rely upon different arrangements, namely detection of emissions from a photoreactive dye and transmission through a sample for absorption measurements, respectively. There is no indication in Kovacs that tissue or debris would negatively affect the measurement obtained with the dye, and further, Kovacs indicates the desirability of contact of the dye

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with the measured environment. Crothall does not indicate that their arrangement is a useful solution for a non-transmitted signal arrangement. As such, there is no motivation to combine these references and the rejection of these claims is withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric F Winakur
Primary Examiner
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1 September 2005

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